Multi-material design and 3D printing method of lower limb prosthetic sockets

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ABSTRACT

The paper shows a research activity aimed at integrating low cost industrial technologies in the design, test and manufacture of medical devices. This work focuses on lower limb prosthesis and in particular on the custom-fit component interacting with the residual limb, i.e. the socket. The process going from the 3D reconstruction of patients' limb to the manufacture of the socket by means of a 3D printer has been designed. Moreover, this must be as automatic as possible and should not require the presence of a design and simulation expert. This implied a deep involvement of physicians and orthopaedic technicians in order to embed rules and procedures in the system. The process is divided in three steps: design, test and manufacture. For each step some details are shown and at last some conclusions are drawn mainly concerning the challenge of multi-material 3D printing of the socket.

CCS Concepts

•Computing methodologies → Virtual reality; Mesh models; •Hardware → Scanners; •Software and its engineering → *Virtual worlds software;*

Keywords

3D printing, Socket Modelling Assistant, Lower Limb Prosthesis

1. INTRODUCTION

The megatrend of virtualization is pervading the medical domain as well as a number of related solutions. Potentially breakthrough ICT technologies are launched on the market every few months but not all the industrial sectors are prone to quickly adopt them. Actually, in the medical field it is required to severely assess the reliability and robustness of any technical novelties, either for diagnostic purpose or for treatment. Two main leverages that can shorten the introduction of new technical solutions in the medical field are (i) a high level of automation in the process, so that any system can perform most of the work without human intervention and (ii) the adoption of high-performing low-cost devices derived from other application sectors (e.g., entertainment or videogaming industry). According to this approach, the paper presents a full-virtual method to design, test and manufacture lower limb prosthesis that in a near future will hopefully take place of traditional empirical method. There are several phases in which HW and SW solutions may be applied. For instance, manual measurement of anthropometric data can be replaced by diagnostic image processing or by 3D scanning to create a 3D model of the anatomical district. Such model can be virtually edited to create the appropriate functional shape according to embedded knowledge. Moreover, some test and validation procedures can be performed on the virtual model before dealing with real components, thus, anticipating potential failures and early fixing otherwise costly issues. At last, manufacturing may rely on the virtual model and 3D printing technology can be profitably used, not only to shorten production times, but to create a high performance customized solution for each patient. The paper, after describing the traditional process to manufacture lower limb prosthesis, shows the proposed methods and tools to accomplish the innovative way to design, test and manufacturing of the prosthesis.

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REHAB '15, October 01-02, 2015, Lisbon, Portugal

© 2015 ACM. ISBN 978-1-4503-3898-1/15/10...$15.00

DOI: http://dx.doi.org/10.1145/2838944.2838955

2. LOWER LIMB TRADITIONAL MANUFACTURING PROCESS

The socket is the most critical component for both transfemoral and transtibial prostheses. It is manufactured from a positive chalk cast of the residual limb. The cast can be manufactured following a full handmade procedure or partially based on CAD/CAM systems [9]. During traditional manufacturing process, the technician continuously uses the hands to achieve the most functional and comfortable socket shape. At first, s/he does an evaluation of the amputee and creates a negative cast manipulating by hands plaster patches directly on patient's residual limb (Figure 1a). Then, orthopaedic technician builds the positive model by adding and removing chalk in specific zones according to

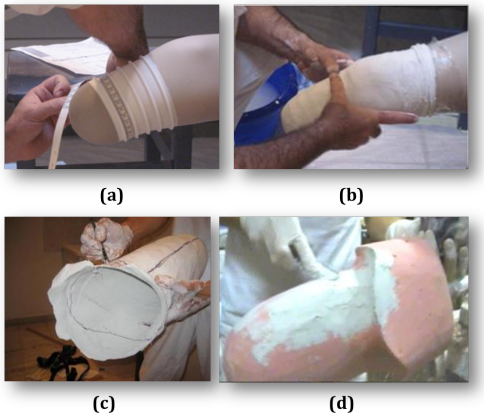


Figure 1: Some of the traditional steps of the socket manufacturing process.

residuum size and patient's features (e.g., muscles tonicity). Three main manual operations are performed: initial plaster circumference reduction, identification and marking of critical zones, and critical zones manipulation. As showed in Figure 1b, the first operation consists in a reduction of positive plaster cast according to residual limb conditions. For example, the socket must be more fitting for young or recently amputated patients, while for elderly patients it needs to be a bit loose to allow an easier gait or rehabilitation activities. In the second step (Figure 1c) the technician marks with a pencil on the positive cast the areas that have to be modified. The third step consists in adding or removing materials in highlighted critical zones (Figure 1d). We identified these critical zones, which are different for transtibial and transfemoral amputees, and can be classified in (i) *Load zones* where there are no bony protuberances or tendons. In this case the plaster has to be removed in order to have a self-supporting tighter socket. (ii) *Off-load zones* where there are bony protuberances or tendons. In this case the technician adds material on the positive plaster cast since in that zones the socket does not have to press the limb and be slightly loose. After this, a thermoformed check socket is manufactured directly on the modified positive model and tested on the patient. Other necessary modifications are sketched on the positive model to realize a more comfortable and well-fitting final socket. Finally, the definitive socket is realized and all the prosthesis components are assembled for the final static set-up. Summarizing, the socket is manufactured following a hand-made procedure and the final shape heavily depends on the prosthetist's skills and experience. Even if the socket has been designed starting from patient's features, the socket design does not take in consideration several aspects relative to the material hardness that usually creates fatigue and sickness to the amputees during gate along both load and off-load zones. This issues could be approached by exploiting 3D printing technology.

3. PROPOSED METHOD

The proposed method is centred on the virtual representation of the patient's residual limb. Even if the virtual process is highly integrated and the data flow is as fluid as possible, three main phases can be identified as design, test

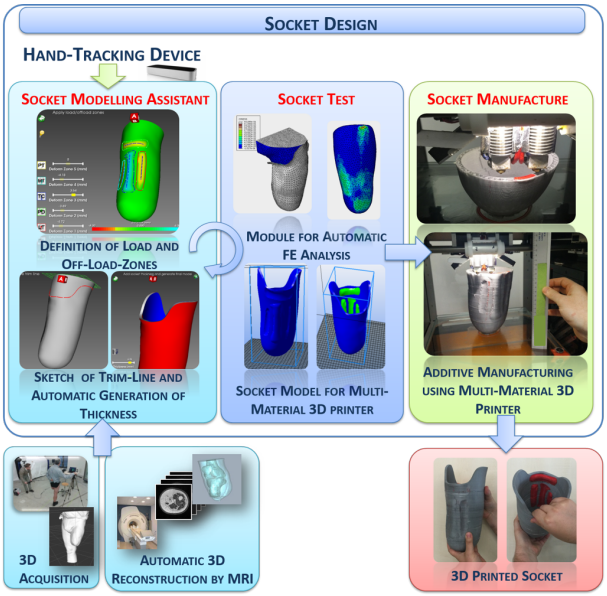


Figure 2: Main phases of proposed method.

and manufacture of socket. As showed in Figure 2, firstly the technician uses SMA to design the initial socket shape. Then, a pressure analysis is executed until the best socket shape has been achieved. After that, STL files are exported by SMA according to chosen materials for both load zones and the rest of socket. Finally, a multi-material 3D printer is used to build the socket.

3.1 Socket Modelling Assistant

In the last decade, our research group has been developing an ad-hoc knowledge-guided CAD system which allows the prosthetist to design the socket of both transtibial and transfemoral prosthesis relying on the digital model of the residual limb (Figure 2) [2]. Socket Modelling Assistant (SMA) emulates all phases of the socket development process starting from the digital model of the residual limb acquired either by Magnetic Resonance Imaging (MRI) or using a low cost RGB-D depth sensor. The prosthetist is guided step-by-step by the system that applies in automatic or semi-automatic way the rules and the modelling procedures. As showed left rectangular box of Figure 2, SMA embeds a set of design rules and procedures (e.g., where and how to modify the socket shape, automatic generation of trimline as well as marking load and off-load zones) and makes available a set of interactive virtual tools to manipulate the socket shape according to traditional procedures. Furthemore, we have developed a module which exploits hand-tracking devices (e.g., Leap Motion device) in order to emulate the design operation as traditionally made by orthopedic technicians who use their hands to shape the socket [3]. Beyond the technical challenge of creating such a complex ICT tool, the relevance of this part is mainly due to the inner connection it has with the medical application. The module has been built exploiting orthopaedic knowledge extracted from physicians interviews and best cases, coded and embedded into the system. Moreover, the real applicative condition in an prosthetic lab has been kept in high consideration while designing the process and the user's interface. This should

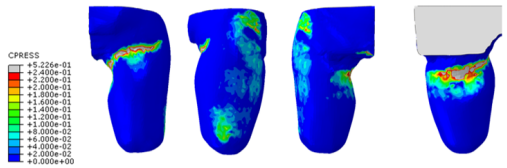


Figure 3: Pressure map obtain with FE simulation between residual limb and socket.

ease the transition to a digital way of designing the socket.

3.2 Socket Test

The design of the socket is performed taking into account several patient's features and, thus, the result achieved is supposed to be very close to the desired one. By the way, there are some characteristics which can be hardly modelled in the design phase, as the residual limb mechanical properties and its deformation during the donning and the gait. Such results can be achieved by means of a contact pressure numerical simulation. The main challenge of this phase has been to implement an automatic procedure to provide the medical staff with Finite Element simulation results without the intervention of a simulation expert. Moreover, the outcome of simulation highlights eventual pressure peaks or other issues that can be passed to SMA in order to be automatically fixed. The numerical simulation required the definition of a number of parameters guiding the process and of simulations rules related to: geometric model, mesh, material characterization, analysis steps, and boundary conditions. They have been derived from an extensive analysis of the state of the art, from the experience acquired in previous research activities, and by balancing accuracy of results and computational costs. Details about the SW tools, the 3D model definition and the simulation parameters can be found in [4, 7]. As said simulation results can be handled in background so that no expert is required, by the way to control the shape change operated by SMA a graphical representation of the pressure distribution can be shown (Figure 3). Once the iterations among the design and test phases is completed, i.e. when the patient's load does not create critical pressure conditions, the output can be generated in order to proceed with the socket manufacture. SMA automatically exports two STL files, corresponding to the load and off-load zones and, thus, the different material to be used for the manufacturing.

3.3 Socket manufacture

New technologies permitted an evolution in the project phase: the possibility to migrate from traditional manual methods to virtual 3D design is breakthrough change. Additive manufacturing allows creating real models which are already usable for testing and simulation. In the last years the development of this application field was very quick. Thus, the global market is full of 3D printing modes, materials, machines and other variants. In this way many challenge are born in a lot of field such as industrial, design, medical, scientific or daily scopes [1]. The range of materials that is possible to use in 3D printing application is very large and constantly growing. Plastic materials, bio-materials, steel, ceramic, clay are just a few that can be printed nowadays. FDM (Fuse Deposition Modeling) is a 3D printing method

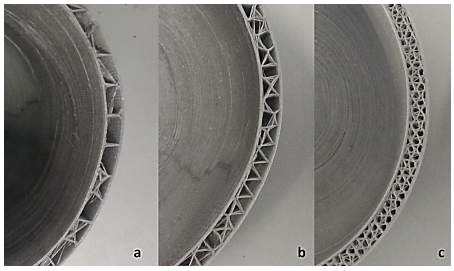
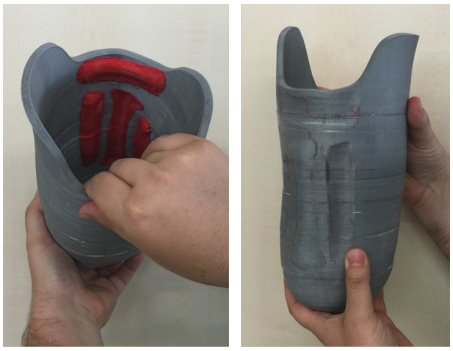


Figure 4: Several infill modes: a) 5% b) 10% c) 20%

that consist in the extrusion of fused material on the printing plane by layers [8]. The deposition of a lot of layers permits the creation of a 3D model. This process is used especially with plastic filaments of different composition like PLA, ABS or HIPS [6]. Using this filaments, it is important to take care to the warping caused by the fusion and the fast cooling during the deposition process. PLA (Polylactic acid or polylactide) is a biodegradable thermoplastic polyester derived from renewable resources and it is the most used one. These are the main materials used in 3D plastic printing, but there are some special filaments for particular uses like flexible filaments, that are made with a rubber material permitting great deformation, or water soluble filaments useful to realize supports easy to be removed. This variety of printing filaments allows the integration of multiple materials in the same object: in this way it is possible to realize object with different composition areas. Taking advantage of flexible material and multi-material print possibility, new 3D printer permits to create object with soft and hard parts. Another important parameter is the infill density and shape. The internal structure conferred to the printed component contributes substantially to confer it rigidity and deformability. The internal grid can follow a twisted rectangular shape, honeycomb or round path (Figure 4). The relationship between internal grid shape and the features of the part is very strong: the internal structure is manually created in relation to the stiffness required by the component. The transformation from 3D model to 3D geometry ready to be printed is the base to obtain multi-material object. The different characteristics of the volumes, obtained by varying the density through the fill and the different materials, is the most important element that gives the socket the local mechanical characteristics necessary to find a good compromise between comfort and structural strength. All these simulations and methods were applied to a case study with a patient with a lower limb prosthesis. This patient is a middle age man without the left leg and he uses a transtibial prosthesis. The study focused on the creation of an adaptive socket based on the residual limb geometry of the patient. In this application the socket composition was determinated in relation to load and off-load area of the socket: external coating is made with hard material, internal surface is composed by different area made of soft material for off-load zone and hard material for load zone. Off-load zones have not to support excessive loads but should only ensure structural strength and comfort to the patient. Load zones, conversely, must ensure a good compromise between mechanical resistance and comfort: they have to support all the height of the person and at the same time guarantee a full painless contact. In this paper all issues about infill, materials and



(a) (b)

Figure 5: Interior (a) and exterior (b) of the 3D printed socket.

comfort were engaged and solved with solutions with different compositions of materials. Generally we use PLA with different infill density for hard areas and a rubber material for soft zones. The socket was realized with the 3D printer "Leonardo 300 Cube" by Meccatronicore (Figure 5). This printer permits the multi-material printing with two different extruders. The application target is to obtain a perfect socket based on the residual limb geometry that guarantees a comfortable fit and an ideal matching. This approach avoids the patient to do several orthopaedic visits to correct socket shape.

4. CONCLUSIONS

Emerging technologies such a low-cost 3D scanners or 3D printing have a potential huge impact in several applications in which real life habits or custom fit products are involved. By the way, in some domains the level of robustness and required reliability are much higher than the lever provided by emerging technologies and this slows down the innovation process. It also happens frequently that new technological solutions require an expert of the domain in which the technology has been developed and this is conflicting with the low-cost approach. The research work shown in this paper, beyond the technical complexity of the engineering solutions developed, is focused on the real usability of the final solutions for a non-technical operator. The underlying approach consists in on one hand in embedding into the system all the routine and standard pieces of knowledge, rules and parameters; on the other hand the intervention of the operator is asked whenever a decision making step is required. According to this approach, the design, test and manufacture of lower limb prosthetic socket has been radically changed. The traditional process is not computer aided and strictly relies on the manual ability of the prosthetist. The method and the tools proposed, on the contrary, are aimed at creating a 3D virtual representation of the residual limb, so that each design action can be performed on the digital model of the product rather than on a physical mock-up. The test can be performed without involving the patient and adopting his/her avatar to perform donning, static loading and gait simulations. The feasibility of each of these single phases have been already investigated in previous works [4, 5]and what was still missing is a complete process going from patient data acquisition to prosthesis manufacture. The first two phases of the proposed procedure, i.e. socket design and socket test have been developed trying to virtually replicate the manual process. This is not true for the last phase in which the state of the art production process consists in laminating a sheet of plastic polymer and to reinforce it with carbon fiber or other tissues. This solution is excellent for mechanical resistance and it is widespread. By the way, the use of additive manufacturing techniques opens at least two great opportunities: (i) the use of 3D internal filling of the socket wall to balance resistance and lightweight and (ii) the combined use of materials with different mechanical properties (e.g., different stiffness) to create hard and soft parts in specific zones of a one piece socket. There are still some open issue on the use of 3D printed materials for daily used sockets. Material is hard to be characterized and, thus, to be approved as safe and reliable. However, the huge diffusion and research carried out in 3D printers will probably fix these issues in a short term and allow to produce robust, lightweight and reliable socket in a near future.

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